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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,179	03/22/2001	Tae-Wan Kim	0609.4910002/JAG/JUK	8573

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EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/814,179	KIM ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *10-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/27/04 has been entered.

1. Formal Matters

A. The Amendment dated 4/27/04 has been entered into the record. Claims 1-41 are pending. Claims 10-40 have been withdrawn as being drawn to a non-elected invention. Therefore, claims 1-9 and 41 are the subject of this Office Action.

B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 1-9 and 41 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 2-3 of the Office Action dated 12/31/03. Applicants argue that they specification provides non-limiting examples of techniques and cells which can be used to practice the claimed invention as well as neurodegenerative diseases. They further argue that in vitro studies provide a nexus to in vivo results since both have been shown to demonstrate the same phenotypic response.

These arguments have been considered and are deemed persuasive in part. The Examiner agrees that the claims are not 'reach-thru' claims. However, the fact remains that the claims recite the screening of compounds/agents which are capable of treating a neurodegenerative disease. Therefore, regarding Applicants' arguments that they have enabled the full scope of the claims with regard to identifying agents capable of treating all neurodegenerative diseases associated with neuronal cell death, Applicants would need to demonstrate that the identified agents are, in fact, able to treat the claimed diseases. To obviate this part of the rejection, if Applicants intend to use a screening method to identify agents which may (as opposed to with certainty) be able to treat a neurodegenerative disease, the claims should be amended to recite "a method of identifying an agent which is a *candidate* for the treatment of a neurodegenerative disease," or "a method of identifying an agent which is *potentially* capable of treating..."

Furthermore, the claim should recite whether the potentiation, or the inhibition of the potentiation of CCE would be the desired endpoint for the treatment of a neurodegenerative disease. For example, adding a conclusion step which states "...and wherein an agent that potentiates CCE would be a potential agent for treating a neurodegenerative disorder." This is especially true with the limitation that the tests are performed in animal studies. Applicants have not taught which animal studies are to be used to measure CCE, and what endpoints in these animal studies will be used to determine a potentiation of CCE in these animals.

3. Claim Rejections - 35 USC § 112, first paragraph - new matter

A. Claims 1-9 and 41 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 3 of the Office Action dated 12/31/03. Applicants argue that the totality of the information provided in the specification would convey to one of skill in the art that Applicants had possession of the claimed invention. This argument has been considered, but is not deemed persuasive. It appears that the specification would imply that the neuronal cell death would be due to apoptosis only. Therefore, it is suggested that the claims be amended to recite "apoptotic neuronal cell death" or "neuronal cell death caused by apoptosis." If Applicants disagree, than further explanation would be required.

4. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 1-9 and 41 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to remove the phrase "associated with."

B. Claims 1-9 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a conclusion step reciting whether the potentiation, or the inhibition of the potentiation of CCE would be the desired endpoint for the treatment of a neurodegenerative disease. For example, adding a conclusion step which states "...and wherein an agent that potentiates CCE would be a potential agent for treating a neurodegenerative disorder." This is especially true with the limitation that the tests are performed in animal studies. Applicants have not taught which animal studies are to be used to measure CCE, and what endpoints in these animal studies will be used to determine a potentiation of CCE in these animals.

5. Claim Rejections - 35 USC § 102

A. The rejection of claim 1 under 35 USC 102(b) as being anticipated by Buxbaum et al. has been withdrawn in view of the fact that the reference teaches screening methods involving intracellular calcium levels, not capacitative calcium entry, as recited in the presently claimed invention.

B. The rejection of claim 1 under 35 USC 102(b) as being anticipated by Berridge et al. has been withdrawn in view of the fact that Berridge do not teach the use of animal testing.

C. The rejection of claims 1, 9 and 41 under 35 USC 102(b) as being anticipated by Birnbaumer et al. has been withdrawn in view of the fact that Birnbaumer do not teach the use of animal testing.

6. Claim Rejections - 35 USC § 103

A. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berridge et al. (Biochem J.). The teachings of Berridge can be seen in the Office Actions dated 5/12/03 and 12/31/03. Berridge do not teach performing screening methods in animal studies. However, it would have been obvious to one of ordinary skill in the art at the time of the present invention to have performed screening methods in animals since this data would provide more useful for the treatment of diseases than simply using cells in vitro. There would have been a reasonable expectation of success for one of ordinary skill in the art to have used animal studies to screen for compounds affecting CCE since animal studies were well-known at the time of the present invention. Again, the fact that the agent identified is capable of treating a neurodegenerative disease is an intended use and does not have any patentable weight. Regardless of the intended use of the compounds, procedures performed for the purpose of potentially treating neurodegenerative disease would be identical to those performed by the artisan simply screening for compounds which affect CCE without knowing the relationship between CCE and neurodegenerative diseases.

B. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Birnbaumer et al. (U.S. Patent 5,932,417). The teachings of Birnbaumer can be seen in the Office Actions dated 5/12/03 and 12/31/03. Birnbaumer do not teach performing screening methods in animal studies. However, it would have been obvious to one of ordinary skill in the art at the time of the present invention to have performed screening methods in animals since this data would provide more useful for the treatment of diseases than

simply using cells in vitro. There would have been a reasonable expectation of success for one of ordinary skill in the art to have used animal studies to screen for compounds affecting CCE since animal studies were well-known at the time of the present invention. Again, the fact that the agent identified is capable of treating a neurodegenerative disease is an intended use and does not have any patentable weight. Regardless of the intended use of the compounds, procedures performed for the purpose of potentially treating neurodegenerative disease would be identical to those performed by the artisan simply screening for compounds which affect CCE without knowing the relationship between CCE and neurodegenerative diseases.

7. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
July 01, 2004

ROBERT LANDSMAN
PATENT EXAMINER